SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING APRIL 28, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on April 28, 1999, at 2 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Mr. Joe Slayton of U.S. Environmental Protection Agency's (EPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. A list of parking lot issues is given in Attachment C. Attachment D presents the QS Committee approach to handling comments, comment acknowledgment form letter, commenter template, and guiding principles for reviewing comments and the standard. Changes to the language in Chapter 5 proposed at this teleconference are reflected in version 5.10.7 of the standard. The purpose of the meeting was to: review action items from the previous teleconference, discuss demonstration of capability, review the combined glossary, select new QS Committee members, and develop the NELAC V agenda.

REVIEW OF ACTION ITEMS FROM THE PREVIOUS MEETING

The committee reviewed the action items from the previous meeting, which was held by teleconference on April 20th. Items not already completed or addressed at today's meeting will be carried over to the next meeting.

DISCUSSION ON DEMONSTRATION OF CAPABILITY (DOC)

<u>Section 5.10.2.1.a</u>: The term *newly accredited* was deleted from paragraph a. The point was raised that laboratories, which use sample spike results for demonstration of capability (DOC), should not be allowed to select only the best results from the previous 12 months. Therefore, the language was changed to: *However, actual sample spike results may be used to meet this standard, i.e., at least 4 consecutive matrix spikes within the last 12 months*

In addition, language was added to allow performing DOC using quality control samples for analytes that do not lend themselves to spiking.

<u>Section 5.10.2.1.a.3</u>: This section was revised so that it specifies the exceptions to the requirements in 5.10.2.1, which are tests for which spiking is not an option and for which Quality Control Samples are not readily available (e.g., microbiology, odor, temperature, and dissolved oxygen).

<u>Section C.1</u>: The language in the introductory chapter was modified to be consistent with the proposed changes to 5.10.2.1.a. In addition, the use of 40 CFR 136 Appendix A for DOC was revised so that:

- it shall be used if required by mandatory test method or regulation, and
- it may be used for analytes for which spiking is not an option and for which quality control samples are not readily available.

<u>Section C.1.a</u>: The language was changed so that a concentration approximately 10 times the method-stated or laboratory-calculated method detection limit shall be used if the concentration is not specified. In addition, editorial changes were made to clarify the meaning of this section.

<u>Section C.1.d</u>: The language about performing calculations was changed to be consistent with Section C.1.c. Language was added to address tests for which calculating a mean and standard deviation is not possible, such as tests for presence/absence.

<u>Section C.1.e</u>: Editorial changes were made clarify the requirements of this section.

<u>Section D.1.4.a</u>: The requirements for when a method detection limit (MDL) study is needed where modified to be consistent with the changes to the DOC requirements. That is, an MDL study is not required for any component for which spiking solutions or quality control samples are not available such as odor and temperature.

DISCUSSION OF THE WORK CELL

Sections 5.10.2.1.e, f, and g were added to address the concept of the work cell. A work cell is defined as: a group consisting of analysts with specifically defined tasks that together perform the test method.

<u>Section 5.10.2.1.e</u>: This new section was created from the note that followed item d.

<u>Section 5.10.2.1.f</u>: This new section addresses the concept of the work cell and training for new members in a work cell, assessing and documenting work cell performance, corrective action if performance is not acceptable, and demonstrating performance again if an entire work cell is changed.

<u>Section 5.10.2.1.g</u>: This new section addresses linking the performance of the work cell to the training records of the individual work cell members (training records are addressed in Section 5.6.2).

Combined Glossary

The committee began reviewing the glossary that was developed by combining the NELAC Glossary and Appendix B (Definitions) from Chapter 5. The committee will continue this review at the next meeting.

NEXT MEETING

The next QS Committee meeting will be by teleconference on Wednesday, May 5th from noon to 1 p.m. EDT. The agenda will include discussing the agenda for NELAC V and selecting new members for the committee as these items need to be completed by May 10th.

ACTION ITEMS QUALITY SYSTEMS COMMITTEE APRIL 28, 1999

Item No.	Action Item	Date to be Completed
1.	Mr. Slayton to forward comments on whole effluent toxicity to the individuals who have agreed to assist in addressing comments on this subject.	
2.	Review Mr. Raymond Frederici's responses to comments from Quanterra on Sections 5.4.2, 5.7.1, and 5.11.3.	
3.	Revisit Mr. David Mendenhall's proposed deletion of the first sentence in the second paragraph of Section D1.1.a.1. Current version of Chapter 5 has deleted this sentence.	
4.	Mr. Slayton to assign and distribute new comments for QS Committee members to address.	
5.	The next teleconference is May 5 th from noon to 1 p.m. EDT.	

PARTICIPANTS QUALITY SYSTEMS COMMITTEE APRIL 28, 1999

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PARKING LOT ITEMS/ISSUES QUALITY SYSTEMS COMMITTEE APRIL 28, 1999

Items/issues will remain in the Parking Lot until they are completed.

1. Air Appendix

Need to review and finalize

2. Initial Demonstration of Capability:

Need to address an IDOC for tests for which you can not spike. Also, does IDOC need to be universal and address all medias? Donivan Porterfield is lead.

3. Definitions/Glossary

Changes necessary to be consistent with Program Policy and Structure proposal. QS Committee will review definitions/glossary at interim meeting.

4. Need to vote in two new members to QS committee.

All candidates must be identified and voted upon by NELAC Committees by May 10, 1999. All appointments by the NELAC Chair must be complete by May 17, 1999.

5. Final QS Chapter for NELAC V

Final changes to standards are due to Research Triangle Institute by April 29, 1999 for posting on the NELAC Web page prior to the annual meeting. This version will be posted within a week and half of receipt and will remain as the final proposed text for Annual Meeting.

6. Agenda for NELAC V

Final committee agendas, including discussion items and times, are due to Elizabeth Dutrow by May 10, 1999.

ACKNOWLEDGMENT LETTER, REVIEW GUIDELINES, and COMMENTER TEMPLATE Quality Systems Committee April 28, 1999

Dear :

Date:

On behalf of the Quality Systems Committee, thank you for your comments on the Chapter 5 standards of the National Environmental Laboratory Accreditation Conference (NELAC). The standards are routinely reviewed and updated. Continual improvement of the standards is the focal point of NELAC process. We encourage your continued written input as well as your attendance at the NELAC interim meeting and yearly conference. Also, our committee routinely schedules 1-2 open forum meetings during each calender year.

Our committee requests that all comments be supplied in electronic format (WordPerfect if possible) and that handwritten, hardcopy and the use of color fonts be avoided. Comments are considered by the QS committee on a first come basis. We have placed a template (table) for comments on the NELAC Web page, which we hope will ensure that the processes is efficient. With this process we hope that emphasis can be placed on consideration of the comments so that the available time is not spent in the mechanics of exchanging information (US Mail and re-typing comments). Routinely, each set of comments is assigned a QS leader who will complete the comment table including suggested language for any proposed changes to the NELAC standards. The Leader will guide a discussion of the comments during routine committee meetings. The minutes of the meeting (posted on the web site) will capture the information in the completed table from committee discussions, thoughts/rationale and present the final decisions.

Again, thank you for taking the time and effort to improve the NELAC Quality System standards.

Sincerely, Joseph Slayton, Chair Quality Systems Committee

QS Approach: Comments Received and QS Response:

- 1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.
- 2. QS will consider the comments in the order received.
- 3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).
- 4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.
- 5. All comments and written responses will be attached to QS meeting minutes.
- 6. <u>No colors</u> to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.
- 7. All comments are to be provided in WordPerfect or rich text format using the following the following table:

GUIDING PRINCIPLES/REVIEW CRITERIA

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

Flexible:

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the "What" and avoid were possible the "How To", (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

Auditable:

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Practical/Essential:

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

Widely Applicable:

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

Appropriate For The Use of the Data:

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

Comment ID #: , Source of Comments (Name): QS Lead on Response (Name):							
Standard Rev. # SECTION#	COMMENTwith Rationale to QS	QS Leader Provided	RATIONAL				
and QS Standard Narrative	(T- D- Ell-1: C	Proposed Change	(from QS Leader)				
(To Filled In by Commentor)	(To Be Filled in my Commentor)	(Commentor Leave	(Commentor Leave				
	New Wording for Standard	Blank)	Blank)				
	(To Be Filled In by Commentor)						

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